DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 12, 2014

Excelsior Medical Corporation
Mr. John Linfante
Vice President RA/QA
1933 Heck Avenue
Neptune, NJ 07753

Re: K142620
Trade/Device Name: 0.9% Sodium Chloride Injection, USP
Regulation Number: 21 CFR 880.5200
Regulation Name: Saline, Vascular Access Flush
Regulatory Class: II
Product Code: NGT
Dated: September 15, 2014
Received: September 16, 2014

Dear Mr. Linfante

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142620

Device Name
0.9% Sodium Chloride Injection, USP

(2.5 mL in 3 mL Syringe, 3 mL in 10 mL Syringe, 5 mL in 10 mL Syringe, 10 mL in 10 mL Syringe)

Indications for Use *(Describe)*

0.9% Sodium Chloride Injection, USP prefilled syringes are intended for flushing of IV catheters and IV tubing only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Manufacturer Name:	Excelsior Medical Corporation
Address:	1933 Heck Avenue Neptune, NJ 07753
Contact Name:	John Linfante
Title:	Vice President RA/QA
Phone Number:	732-643-6088
Fax Number:	732-776-7600
Date Prepared:	September 15, 2014

Device Proprietary Name:	0.9% Sodium Chloride Injection, USP
Device Common or Usual Name:	Saline, Vascular Access Flush
Classification Name:	Saline, Vascular Access Flush
Classification Code:	NGT
Regulation Number:	21 CFR Part 880.5200
Device Classification	II

Predicate Devices:

Substantial equivalence is claimed to the following devices as related to intended use, design, and material characteristics:

- Excelsior Disposable Syringe W/Normal Saline (0.9% Sodium Chloride), Excelsior Medical Corp., K962938
- Sterile Field Saline Flush Syringe(s), Excelsior Medical Corporation, K082837

Description of the Device

Excelsior Medical Corporation's 0.9% Sodium Chloride Injection, USP prefilled syringe products are provided as terminally sterilized, single-use, pre-filled, pre-packaged products. The saline solution is delivered through the luer lock of a venous access device to maintain catheter patency via hydraulic displacement. Typically, the venous access device is flushed with normal saline before and after the administration of intermittent medication therapy, blood sampling, total parenteral nutrition, or hemodialysis.

0.9% Sodium Chloride Injection, USP, prefilled syringes are available as follows:

- 2.5 mL in 3 mL Syringe
- 3 mL in 10 mL Syringe
- 5 mL in 10 mL Syringe

- 10 mL in 10 mL Syringe

The product is intended for use with commercially available valves and catheters fitted with a standard mating luer lock or luer taper.

Intended Use/Indications for Use

0.9% Sodium Chloride Injection, USP, prefilled syringes are intended for flushing of IV catheters and IV tubing only.

Technological Characteristics

The 0.9% Sodium Chloride Injection, USP syringes subject to this filing were previously cleared by FDA under K962938. The use of alternate syringes, application of syringe labels on non-printed barrels, and sterilization via steam were cleared under K082837 for Excelsior's Sterile Field Flush saline syringes.

A comparison of the products is provided in the table below.

	Saline Flush Syringe (Subject Device)	**Sterile Field Saline Flush Syringe(s) K082837**	**Excelsior Disposable Syringe W/ Normal Saline K962938**
Intended use	Flushing of IV catheters and IV tubing only	Flushing IV catheters and IV tubing	Flushing IV catheters and IV tubing
Components	• Barrel – Medical grade polypropylene and silicone lubricant • Plunger – Medical grade polypropylene • Piston – Latex free isoprene rubber • Tip Cap – Medical grade polypropylene and TPE plus colorant	• Barrel – Medical grade polypropylene and silicone lubricant • Plunger – Medical grade polypropylene • Piston – Latex free isoprene rubber • Tip Cap – Medical grade polypropylene and TPE plus colorant	• Barrel – Medical grade polypropylene and silicone lubricant • Plunger – Medical grade polypropylene • Piston – Latex free isoprene rubber • Tip Cap – Medical grade polypropylene and TPE plus colorant
Solution	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP
Max. Fill level	10 mL	10 mL	10 mL
Sterility	Terminally sterilized by steam 10^{-6} SAL	Terminally sterilized by steam 10^{-6} SAL	Terminally sterilized by gamma

Shelf Life	Intended 2 years	2 years	2 years
Syringe Barrel	Not printed Syringe Label contains: • Graduation marks • Lot Number • Expiry Date	Not printed Syringe Label contains: • Graduation marks • Lot Number • Expiry Date	Pre-printed syringe barrel

There are no differences between the subject and predicate device with respect to intended use or technology. The subject device is the exact same device as the predicate device cleared under K962938 with the following exceptions:

- Introduction of alternate sources of syringes
- Introduction of alternate source of saline
- Gradation markings applied via label
- Sterilization method is steam

These differences are addressed via material qualification, process validation, and finished product release testing. In addition, Excelsior Medical has undertaken performance testing to support that the use of an alternate source of saline does not alter the safety and effectiveness of the product.

Non-Clinical Testing

The following studies have been performed or are being relied upon to support the safety and effectiveness of the product:

- Raw material qualification
- Stability Studies
- Sterilization validation
- Extractables/Leachables

Biocompatibility testing on the subject device is not required as the products are exactly the same as the predicate devices with the exception of the source of the sodium chloride raw material.

Conclusion

Based on the analysis presented above and the results of the performance testing, the subject device is as safe and effective as the predicate device. No new or different questions of safety and effectiveness than the predicate device are raised by the changes.

Therefore, it is concluded that the product is substantially equivalent to the identified predicate devices.